HEMOTHERM®

OPERATION MANUAL

MODEL 400CE DUAL RESERVOIR COOLER/HEATER

A GENTHERM COMPANY

Cincinnati Sub-Zero Products, LLC. • 12011 Mosteller Road • Cincinnati, Ohio 45241, U.S.A.
www.cszmedical.com

©Copyright 2017, Cincinnati Sub-Zero Products, LLC. All rights reserved.

SYMBOLS

Consult instructions for use and/or manual before operating

Pump

Cool

Heat

Compressor

Water Temp – Heat

Water Temp – Cool

Temperature Set

Low Water

Test Indicators

Silence Alarm

High Limit

Low Limit

High Heater

Low Heater

Temperature Limit

Operating Instructions or "Important/Caution Information"

Decreasing Temperature

Increasing Temperature

Water Temperature

AC Voltage

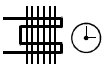
Outlet

Return

Drain

Power Cord Holder

Change Water Monthly


Clean Condenser Monthly

Clean Water Filter Quarterly

Equipotentiality

Protective Earth

Danger; Risk of Electric Shock

Power Fail

Disconnect Power Before Servicing

Earth (Ground)

Risk of Explosion: Do not use in the Presence of Flammable Anesthetics

Type BF Equipment

Fill to Screen

Separate collection for electrical and electronic

HEMOTHERM®
MODEL 400CE
OPERATION MANUAL

Cincinnati Sub-Zero Products, LLC, reserves the right to make equipment changes and improvements which may not be reflected in this manual.

This document may not be reproduced in whole or in part without written permission from Cincinnati Sub-Zero Products, LLC.

HEMOTHERM®, GELLI-ROLL®, MAXI-THERM®, MAXI-THERM® LITE, TEMP-PAD® and PLASTIPAD® are registered trademarks of Cincinnati Sub Zero Products, LLC, Cincinnati, Ohio USA.

©Copyright 2017, Cincinnati Sub-Zero Products, LLC. All rights reserved.

⚠WARNING ⚠
A physician's order is required for use and the setting of equipment and blanket temperature. Check patient's temperature and skin condition of areas in contact with blanket; also, check blanket water temperature at least every 20 minutes, or as directed by physician. Pediatric patients, temperature-sensitive patients with vascular disease, surgical patients, diabetics and Raynaud's disease patients should be checked more frequently. **Notify the physician promptly of any change in patient status in order to avoid serious injury or death.**
The HEMOTHERM is to be operated by a professionally trained perfusionist – with a physician's order for use and the setting of equipment and blanket temperature.
Do not use the HEMOTHERM MODEL 400CE Blankets distal to arterial cross clamping. **Non-observance can lead to thermal injury.**
Thermal injury may occur if heating/cooling blankets are used with a patient with an ischemic limb.
Perfusionist must operate the HEMOTHERM when connected to extracorporeal circuit heat exchanger. **Lack of proper monitoring may result in serious injury or death.**
The operator of the unit regulates the desired fluid temperature. **Frequent observation of the actual blood temperature and body temperature is required.**
Perfusionist must monitor equipment continually during machine operation to ensure there are no "alarms or intervention" required. **Lack of proper monitoring may result in serious injury or death.**
No modification of this equipment is allowed without prior, written authorization from CSZ. **Failure to do so may result in damage to the HEMOTHERM system and/or patient injury.**
The method of temperature control provided by all cooler/heater units presents the danger of heating or cooling body tissues, particularly the skin and or blood, to a point where they are injured, i.e., burns or frostbite, respectively**. Depending on the extent and severity of a burn, very serious and even fatal complications may arise.**
Prevent excessive and/or prolonged tissue pressure and shearing forces, especially over bony prominences. **Failure to do so may result in tissue injury.**
Do not place additional heat sources between the patient and blanket. **Skin damage may result.**
Prep solutions have been reported to injure the skin when allowed to remain between patients and a water-circulating heating blanket during prolonged procedures. **The area between the patient and the blanket should be kept dry to avoid injury to patient.**
Proper sanitation procedures must be practiced and hygienic safety must be maintained, to prevent contamination. Contamination can affect patient's health, i.e. skin irritation/rash or sepsis and infection may result.
Upon receipt of the HEMOTHERM, the unit should be disinfected per the WATER SYSTEM CLEANING & DISINFECTION PROCEDURE. Additionally, any unit removed from storage should be disinfected. **Failure to do so could result in patient and/or caregiver infection.**
Do not use the HEMOTHERM system in the presence of flammable anesthetics. **Risk of explosion can result.**
Power interruption will cause the HEMOTHERM to revert to **FILL MODE** resulting in no therapy to the patient. Follow instructions for desired mode to resume operation. **Failure to resume therapy could result in serious injury or death.**

⚠WARNING ⚠
Any time water is found leaking into or around the unit, connecting hose, and/or blanket, turn the unit off, disconnect the power cord from its power source, and correct the problem before proceeding. **Water leaks could lead to electric shock. Water leaks could present a slip and/or fall hazard.**
Proper sanitation procedures should be followed including, but not limited to, the preventative maintenance described in this manual. Leaky blankets or hoses, as well as unapproved blankets or hoses should never be used. **Water leaks present a risk of infection and should be handled accordingly.**
Contaminated blankets or hoses could contaminate the unit. Reusable accessories should be disinfected on a quarterly basis. **Failure to do so could result in patient and/or caregiver infection.**
Exercise extreme caution if the unit is used for patients who are electrically susceptible (probe, catheter, or electrodes connected to the heart). **Electrical Hazards may result.**
Materials of good thermal conductivity, such as water, gel and similar substances on the blanket, with the HEMOTHERM not switched on **may decrease the temperature of the patient.**
Do not position unit near any objects that can generate a strong electrical/magnetic field. Unit has been investigated to be in compliance with IEC 60601-1-2. **Potential electromagnetic interference may result.**
The repair, calibration, and servicing of the HEMOTHERM should be performed by qualified Medical Equipment Service Technicians, Certified Biomedical Electronics Technicians, or Certified Clinical Engineers familiar with good repair practices for servicing medical devices, and in accordance with instructions contained in this manual. **Improper repair can result in damage to the HEMOTHERM system and patient injury.**
The HEMOTHERM must be serviced and/or preventive maintenance must be performed at specific intervals as outlined in the manual. **Improper repair and inadequate maintenance can result in damage to the HEMOTHERM system and patient injury.**
Always unplug the unit before accessing internal components during service. **Failure to unplug the unit could result in electric shock.**
Before returning the HEMOTHERM to patient use **after** repairs, the FIRST TIME SET-UP/SYSTEM TEST ROUTINE must **always** be performed. **Improper repair and inadequate maintenance can result in damage to the HEMOTHERM system and/or patient injury.**
Remove the HEMOTHERM from service if the outer casing or key pad is cracked or internal components are exposed. **Contact with internal components could result in electric shock or thermal injury to the patient or operator. Additionally, the patient or operator could be exposed sharp edges.**
Before performing any disassembly procedure, be sure the power switch is in the OFF/"O" position and the power cord is unplugged from the receptacle. **Electrical Hazards may result.**
Keep HEMOTHERM grille and condenser clean and free of debris and obstruction. Cool air is taken in through the grille and warm air is evenly expelled through the bottom of the unit. Both the air intake and outlet must be kept clear when the machine is in operation. **Blockage of the grille and condenser could result in the unit overheating which could render the unit unable to provide adequate therapy and excessive surface temperatures could cause injury to patient or operator. Keep unit, specifically the grille away from curtains or other obstructions.**

⚠WARNING ⚠
Do not use an adapter plug to by-pass the plug ground lug. **Electrical Hazards may result.**
Use only 20 Amp hospital grade receptacles or electric shock may result. (US only)
The HEMOTHERM unit has **UL/IEC 60601-1 Class I, type BF applied parts** and it should be noted that internal and external electrically isolated components must remain isolated before, during and after any maintenance or repair. **Improper maintenance or repair can result in patient injury or damage to the HEMOTHERM unit.**
To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
Inspect all blankets for mechanical damage before use. Do not use in proximity to sharp objects. **Blanket punctures can result in an increased risk of infection or electrical shock**.
The warming of transdermal medications (patches) **can increase drug delivery, resulting in possible injury to the patient.**
If a means is needed in restraining a patient either on or under a CSZ Hyper-Hypothermia Blanket or the Connecting Hose, the means should not block the fluid pathways of the HEMOTHERM unit. **Failure to do so may result in inadequate treatment.**
Immediately remove from service and clean & disinfect devices that show discoloration or cloudiness in the fluid lines/circuits. **Failure to do so could result in patient and/or caregiver infection.**

⚠CAUTION ⚠
• Caution: Federal law restricts this device to sale by or on the order of a physician.
• Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. Do not use deionized water. Do not use alcohol. Alcohol may cause heat exchanger, blanket, and/or unit deterioration. Do not use tap water to rinse, fill, refill or top-off water tanks.
• Do not operate without water, to avoid damage to internal components.
• Do not overfill. Overfilling may result in overflow when the water in the blanket drains back into the system when the system is turned off.
• Be careful to not put any strain on any of the electrical cables connected to the circuit boards.
•
• Working with electronic boards, plugs, and cables requires delicate handling. Proper Electrostatic Discharge procedure should be followed during replacement of any electronic board.
• For safe handling and use of chemicals follow manufacturer guidelines.

TABLE OF CONTENTS

Page No.

TECHNICAL HELP 11
AUTHORIZED EUROPEAN REPRESENTATIVE: 11
BEFORE YOU CALL FOR SERVICE... 11
IN-WARRANTY REPAIR AND PARTS 11

RECEIVING INSPECTION 11

IMPORTANT SAFETY INFORMATION 11

SHIPPING PARTS 12

WORLDWIDE ORDER PLACEMENT 12

SECTION 1. INTRODUCTION 13

1.1 GENERAL SAFETY PRECAUTIONS 13
1.2 INTENDED USE 14
1.3 DESCRIPTION, EXTERNAL FEATURES AND PRODUCT PARTS 14
1.4 FUNCTION OF HEMOTHERM MODEL 400CE COOLER/HEATER 20
1.5 COOLING SYSTEM 21
1.6 HEATING SYSTEM 21
1.7 WATER CIRCULATION SYSTEM 22
1.8 GENERAL OPERATION 23
1.9 REMOTE CONTROL OPTION 27
1.10 HEMOTHERM SYSTEM EQUIPMENT & ACCESSORIES 27
1.11 HEMOTHERM SYSTEM EQUIPMENT SPECIFICATIONS 29
1.12 ESSENTIAL PERFORMANCE TABLE 31
1.13 HEMOTHERM CLASSIFICATION AND CERTIFICATIONS 31

SECTION 2. OPERATING INSTRUCTIONS 35

2.1 INITIAL SET-UP 35
2.2 CONNECTION PROCEDURE 36
2.3 DISPOSAL OF WASTE PRODUCTS 36
2.4 SAFETY CONTROLS 37

SECTION 3. MAINTENANCE AND REPAIR 38

3.1 GENERAL 38
3.2 EXTERNAL CLEANING INSTRUCTIONS 38
3.3 TEMPERATURE ACCURACY CHECK 38
3.4 MAINTENANCE OF THE WATER RESERVOIRS 39
3.6 MAINTENANCE OF THE WATER FILTER 42
44
3.7 MAINTENANCE OF THE CONDENSER GRILLE 44
3.8 MAINTENANCE OF THE HYPER-HYPOTHERMIA BLANKETS 44
3.9 REMOVE FROM SERVICE ALARM (RFS) 45
3.10 REQUIRED QUARTERLY PREVENTIVE MAINTENANCE CHECKLIST 47
3.11 REQUIRED MONTHLY PREVENTIVE MAINTENANCE CHECKLIST 48

LIST OF ILLUSTRATIONS

Page No.

FIGURE 1-1, UNIT FRONT PARTS VIEW 15
FIGURE 1-2, KEYPAD – 115V UNIT 17
FIGURE 1-3, KEYPAD – 115V REMOTE 17
FIGURE 1-4, KEYPAD – 230V UNIT 18
FIGURE 1-5, KEYPAD – 230V REMOTE 18

TECHNICAL HELP

United States and Canada
Cincinnati Sub-Zero Products, LLC
12011 Mosteller Road
Cincinnati, OH 45241

Telephone 1-513-772-8810
Toll Free 1-800-989-7373
Fax 1-513-772-9119
Technical Support 1-888-437-5608
Clinical Support 513-460-2038

AUTHORIZED EUROPEAN REPRESENTATIVE:

EC REP CEpartner4U, BV
Esdoornlaan 13
3951 DB Maarn
The Netherlands
www.CEpartner4U.com

BEFORE YOU CALL FOR SERVICE...

To help us better serve you, please have the serial number of your HEMOTHERM unit ready when you call for parts or service. The serial number is located on the side panel of the unit along with the part number.

IN-WARRANTY REPAIR AND PARTS

All parts on your Hemotherm unit are covered by a one-year warranty. To return defective parts or units, first obtain a Returned Materials Authorization (RMA) number from our Medical Technical Service department. A Hemotherm shipping carton will be sent to you, if needed.

NOTE: There is a service charge for a replacement shipping carton**.**

RECEIVING INSPECTION

After unpacking the HEMOTHERM System, be sure to inspect the system for concealed damage. Retain all packing material and carefully describe or photograph any damage. Notify the carrier at once and ask for an inspection (in writing). Failure to do this within 15 days may result in loss of claim. Do not return the equipment to Cincinnati Sub-Zero. Call our Medical Technical Service department for further instructions. Refer to the section TECHNICAL HELP for phone numbers.

IMPORTANT SAFETY INFORMATION

Refer to this manual for instructions and caregiver information. Read and understand all precautionary information before using, prescribing, or servicing the HEMOTHERM unit.

In order to minimize risk of contamination and/or infection, the unit should be disinfected per the WATER SYSTEM CLEANING & DISINFECTION PROCEDURE prior to its first use and at a minimum on a quarterly basis.

SHIPPING PARTS

Parts to be returned to the factory must be carefully packaged, especially the circuit boards. These boards should be cushioned in static safe packaging material to prevent damage from Electro Static Discharge (ESD).

NOTE: SHIPPING DAMAGE WILL BE THE RESPONSIBILITY OF THE SHIPPER. INSURE IF NECESSARY.

NOTE: IF CIRCUIT BOARDS ARE NOT SHIPPED IN STATIC SAFE PACKAGING, WARRANTY WILL BE VOID.

If shipping complete unit, to avoid freezing or damage to packaging, **the entire system must be drained before shipping**.

Worldwide Order Placement

United States and Canada

Telephone..... 1-513-772-8810
(U.S.) Toll Free..... 1-800-989-7373
Fax..... 1-513-772-9119

Healthlink Europe
Burgemeester Burgerlaan 40
5245 NH Rosmalen (Den Bosch)
The Netherlands

SECTION 1. INTRODUCTION

To provide the maximum patient safety during the use of the HEMOTHERM Model 400CE Dual Reservoir Cooler/Heater system, a thorough knowledge and understanding of the system, and its correct application and operating use are required. Each person who is responsible for use or direction of use of the system, such as physicians, perfusionists, technicians and operators must read and understand this operating manual and all precautions and warnings prior to use. It is recommended that this manual be reviewed at least semi-annually as a refresher for safe operation and application. For proper knowledge and understanding, in-service is available upon request.

All service associates, who interface with this equipment, must read and understand this **Operation Manual** in its entirety prior to maintaining or operating the equipment.

1.1 GENERAL SAFETY PRECAUTIONS

The HEMOTHERM has internal self-diagnostics that could prevent the equipment from operating improperly. The most serious of these are the Remove from Service (RFS) alarms. The RFS alarms will require the equipment to be repaired immediately. They are indicated by an “EE” on the Heat side temperature display and a number on the Cool side temperature display. Too high of a temperature in the heat reservoir is also an RFS alarm and will be indicated by the appropriate red LED indicator. All RFS alarms will be announced by an audible alarm that cannot be muted.

High and low temperature limiting thermostats are preset at the factory and should perform satisfactorily for the life of the HEMOTHERM unit. Except for refrigeration component repairs, the repair and servicing of the HEMOTHERM unit requires no special tools. However, no attempt should be made to perform any of the repairs or service procedures outlined in this manual unless the proper skills and knowledge are possessed.

If water is found leaking into or around the HEMOTHERM unit prior to or during the operating procedure discussed here, immediately disconnect power to the unit and correct the malfunction before proceeding.

Before performing any disassembly procedure, press the power switch to the OFF/“O” position and unplug power cord from receptacle.

Exercise extreme caution if this equipment is used on electrically susceptible patients (probe, catheter or electrodes directly connected to the heart). Always test for current leakage before returning unit to service. Additional warnings are expressed at appropriate points in the manual.

See the Warnings and Cautions in the front of this manual.

1.2 INTENDED USE

The HEMOTHERM® Model 400CE Dual Reservoir Cooler/Heater is used to lower, maintain, or raise the temperature of the water flowing through a Blood Oxygenator / Heat Exchanger that is used to cool or warm blood during cardiopulmonary bypass procedures lasting six hours or less. The Hemotherm Dual Reservoir Cooler/Heater may also be used with a hyper / hypothermia blanket under the patient to provide warming through conductive heat transfer.

The HEMOTHERM is capable of delivering temperature controlled water to blood heat exchanger(s) and one (1) blanket in the full range of controllability between 3°C - 42°C.

There are many variables that affect the heating or cooling of the patient in the extracorporeal circuit. Some of these include the patient's weight, blood flow, gas flow and oxygenator/heat exchangers. The HEMOTHERM has been designed to provide high water flow rates at low pressure for safe and highly efficient operation with a blood oxygenator/heat exchanger.

The HEMOTHERM can help maintain normal body temperature (normothermia) particularly during lengthy surgical procedures or where the ambient (room) temperature is set low. This can be done with the use of a Hyper-Hypothermia blanket underneath the patient.

1.3 DESCRIPTION, EXTERNAL FEATURES AND PRODUCT PARTS

The HEMOTHERM Model 400CE Dual Reservoir Cooler/Heater consists of a primary unit that has a water cooling system and a water heating system. These share a common pump, filter and distribution outlet connections. Each water cooling/heating system has its own reservoir, cooler/heater hardware, water level switch, temperature sensor and associated plumbing.

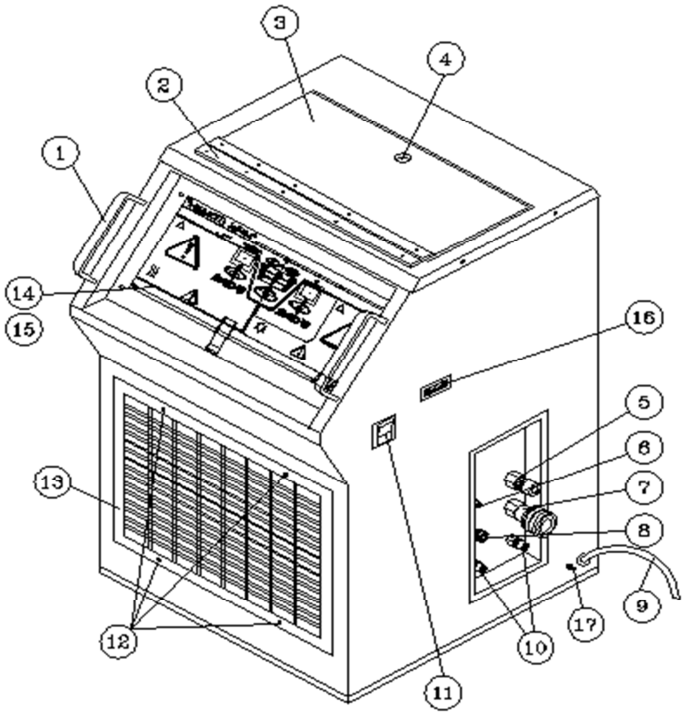


FIGURE 1-1, UNIT FRONT PARTS VIEW

Reference Figure 1-1, Unit Front Parts View

1. HANDLES - The handles permit the operator to grip the unit when moving.

2. CONTINUOUS HINGE – Provides durable smooth lid operation.

3. RESERVOIR LID – Covers the reservoir area.

4. LID HANDLE – Allows the user to easily grip the lid for opening.

5. 1/2 INCH QUICK-CONNECT PLUG OUTLET – This fitting is for the connection of the tubing that is connected to the user provided heat exchanger.

6. 1/8 INCH QUICK-CONNECT PLUG OUTLET – This fitting is for the connection of the tubing that is connected to the user provided optional blanket.

7. 1/2 INCH QUICK-CONNECT SOCKET INLET – This fitting is for the connection of the tubing that is returned from the user provided heat exchanger.

8. 1/8 INCH QUICK-CONNECT SOCKET INLET – This fitting is for the connection of the tubing that is returned from the user provided optional blanket.

9. MAINS POWER CORD – For connection to the mains power receptacle.

10 1/4 INCH QUICK-CONNECT DRAIN OUTLETS – The left outlet drains the cool reservoir. The right outlet drains the heat reservoir.

11 MAINS POWER SWITCH – Controls power to the entire unit and the remote control (if it is connected). Includes integrated circuit breaker for unit over-current protection.

12. GRILLE SCREWS – Allow easy access to clean the front of the condenser.

13. GRILLE – Provides air flow and protection to the condenser.

14. KEY PAD – Main control interface for all unit operations.

15. CONTROL BOARD (behind keypad) – Electronics package with precision dual microprocessor control and redundant water temperature safeties.

16. REMOTE CONTROL PORT – For connection of extension cables that lead to the Remote Control, Model 414CE. One or two 25 foot cables may be used for a maximum reach of 50 feet.

17. EQUIPOTENTIALITY GROUND – Provided to allow connection to the patient area common equipotential ground system.

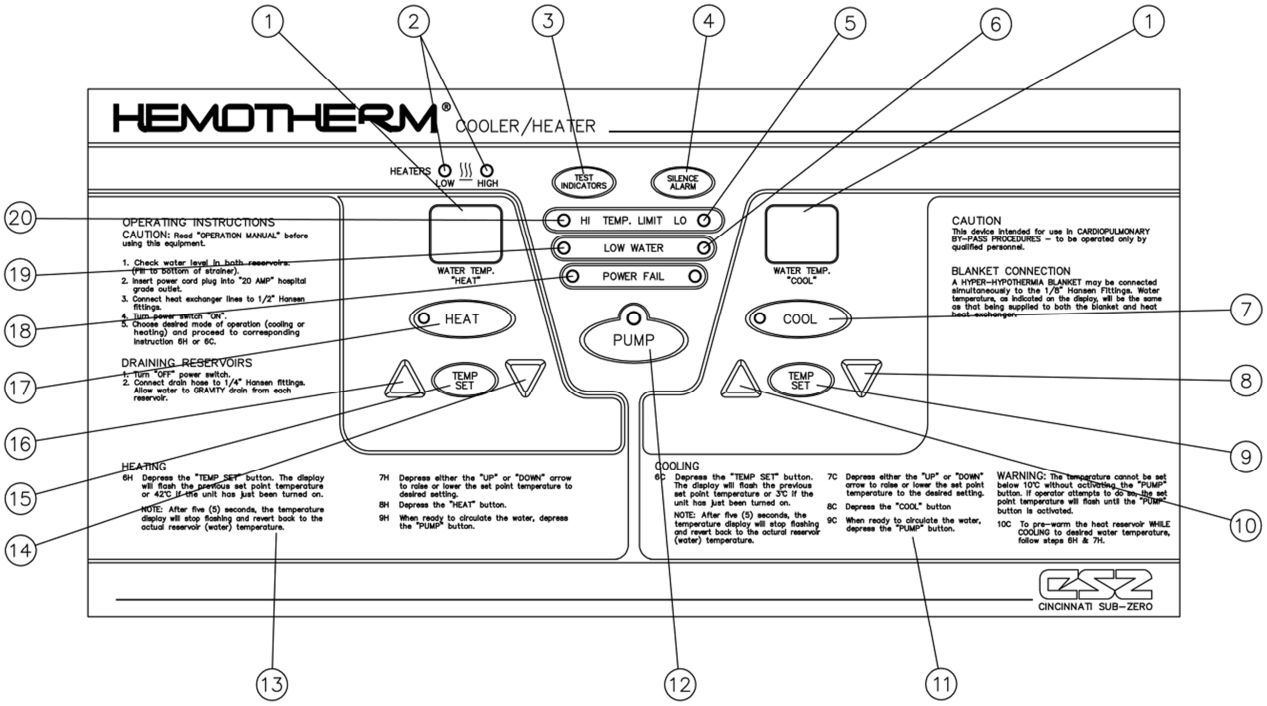

HEMOTHERM® COOLER/HEATER
HEATERS LOW HIGH
TEST INDICATORS
SILENCE ALARM
HI TEMP. LIMIT LO
LOW WATER
POWER FAIL
WATER TEMP. "HEAT"
WATER TEMP. "COOL"
HEAT
COOL
PUMP
TEMP SET
OPERATING INSTRUCTIONS
CAUTION: Read "OPERATION MANUAL" before using this equipment.
1. Check water level in both reservoirs. (Fill to bottom of strainer).
2. Insert power cord plug into "20 AMP" hospital grade outlet.
3. Connect heat exchanger lines to 1/2" Hansen fittings.
4. Turn power switch "ON".
5. Choose desired mode of operation (cooling or heating) and proceed to corresponding instruction 6H or 6C.
DRAINING RESERVOIRS
1. Turn "OFF" power switch.
2. Connect drain hose to 1/4" Hansen fittings. Allow water to GRAVITY drain from each reservoir.
CAUTION
This device intended for use in CARDIOPULMONARY BY-PASS PROCEDURES – to be operated only by qualified personnel.
BLANKET CONNECTION
A HYPER-HYPOTHERMIA BLANKET may be connected simultaneously to the 1/8" Hansen Fittings. Water temperature, as indicated on the display, will be the same as that being supplied to both the blanket and heat exchanger.
HEATING
6H Depress the "TEMP SET" button. The display will flash the previous set point temperature or 42°C if the unit has just been turned on.
NOTE: After five (5) seconds, the temperature display will stop flashing and revert back to the actual reservoir (water) temperature.
7H Depress either the "UP" or "DOWN" arrow to raise or lower the set point temperature to desired setting.
8H Depress the "HEAT" button.
9H When ready to circulate the water, depress the "PUMP" button.
COOLING
6C Depress the "TEMP SET" button. The display will flash the previous set point temperature or 3°C if the unit has just been turned on.
NOTE: After five (5) seconds, the temperature display will stop flashing and revert back to the actual reservoir (water) temperature.
7C Depress either the "UP" or "DOWN" arrow to raise or lower the set point temperature to the desired setting.
8C Depress the "COOL" button
9C When ready to circulate the water, depress the "PUMP" button.
WARNING: The temperature cannot be set below 10°C without activating the "PUMP" button. If operator attempts to do so, the set point temperature will flash until the "PUMP" button is activated.
10C To pre-warm the heat reservoir WHILE COOLING to desired water temperature, follow steps 6H & 7H.
CINCINNATI SUB-ZERO
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

FIGURE 1-2, KEYPAD – 115V UNIT

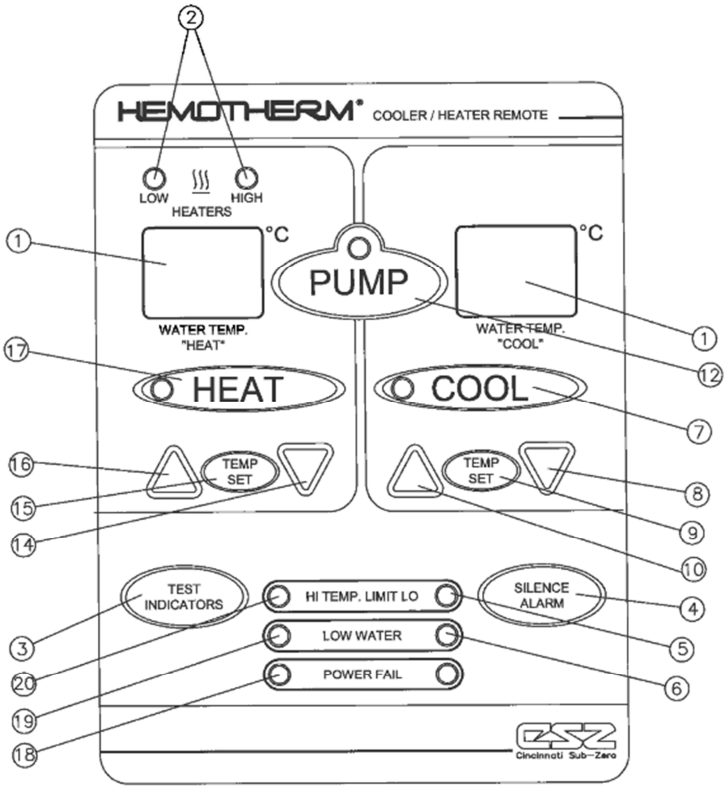


FIGURE 1-3, KEYPAD – 115V REMOTE

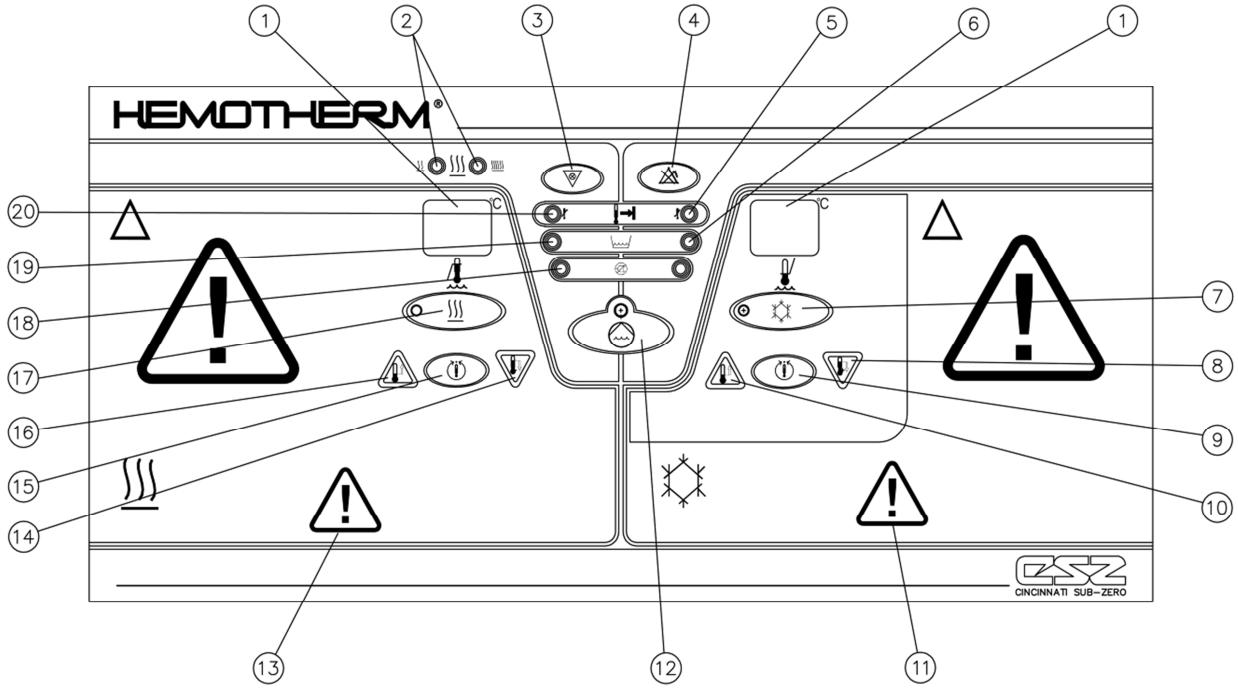


FIGURE 1-4, KEYPAD – 230V UNIT

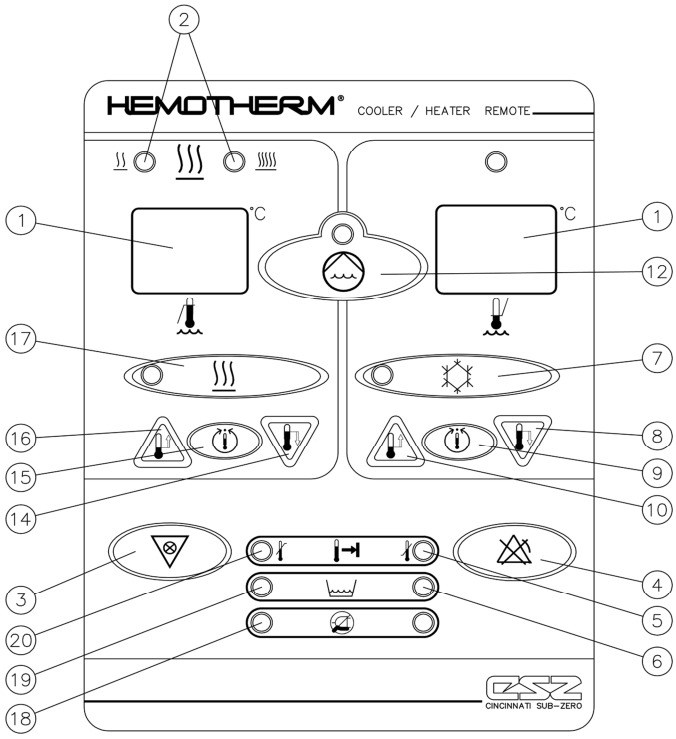


FIGURE 1-5, KEYPAD – 230V REMOTE

Reference Figures 1-2, 1-3, 1-4, & 1-5 Keypad Views

1. TEMPERATURE DISPLAY WINDOWS – Left side indicates heat reservoir temperature. Right side indicates cool reservoir temperature. This display is also used to display the set point temperature when the control is in the temp set mode.

2. HEATER STATUS LIGHTS – When illuminated these indicate that the controller is signaling the heaters to be on. These lights will not indicate a heater that is malfunctioning or inoperative due to a burned out heater element or wire break.

3. TEST INDICATORS BUTTON – When pressed this button will turn on all of the keypad indicators and test the audible alarm.

4. SILENCE ALARM BUTTON – When pressed this button will temporarily silence the alarm if it is not a Remove from Service (RFS) issue.

5. LOW TEMP LIMIT LIGHT – When illuminated the cool reservoir temperature is lower than should be allowed by the safety limits.

6. COOL LOW WATER LIGHT – When illuminated water needs to be added to the cool reservoir. Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns.

7. COOL MODE BUTTON / LIGHT – When pressed this button along with the pump button will start the cool reservoir conditioning to obtain the indicated set point temperature. The light will be illuminated when the unit is in cool mode.

8. COOL DECREMENT BUTTON – When pressed this button will decrease the temperature set point indicated on the cool temperature display.

9. COOL TEMP SET BUTTON – When pressed this button will indicate the desired set point temperature of the cool reservoir on the cool temperature display.

10. COOL INCREMENT BUTTON – When pressed this button will increase the temperature set point indicated on the cool temperature display.

11. COOL INSTRUCTIONS – Abbreviated instructions on how to adjust and set the cool reservoir temperature. To completely understand the operation of the unit, consult appropriate sections in this manual.

12. PUMP BUTTON – When pressed this button will turn on the pump that circulates water in and out of the unit. This button must be pushed after the cool button is pushed if you want to cool the water in the cool reservoir or for unit preconditioning. The pump does not need to be on to allow the heaters to come on. The light will be illuminated when the controller is signaling the pump to operate.

13. HEAT INSTRUCTIONS – Abbreviated instructions on how to adjust and set the heat reservoir temperature. To completely understand the operation of the unit, consult appropriate sections in this manual.

14. HEAT DECREMENT BUTTON – When pressed this button will decrease the temperature set point indicated on the heat temperature display.

15. HEAT TEMP SET BUTTON – When pressed this button will indicate the desired set point temperature of the heat reservoir on the heat temperature display.

16. HEAT INCREMENT BUTTON – When pressed this button will increase the temperature set point indicated on the heat temperature display.

17. HEAT MODE BUTTON / LIGHT – When pressed, this button will put the unit in heat mode. It will start the heat reservoir conditioning to obtain the indicated set point temperature. Unlike the cool mode button this button will allow the heaters to turn on independent of the pump operation. The light will be illuminated when the unit is in heat mode.

18. POWER FAIL LIGHTS – When illuminated these lights will flash alternately to indicate that during operation, the unit has become unplugged or otherwise lost power and the power switch was in the on position.

19. HEAT LOW WATER LIGHT – When illuminated water needs to be added to the heat reservoir. Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns.

20. HEAT HIGH TEMP LIMIT LIGHT – When illuminated the heat reservoir temperature is higher than should be allowed by the safety limits.

1.4 FUNCTION OF HEMOTHERM MODEL 400CE COOLER/HEATER

The HEMOTHERM Model 400CE Cooler/Heater is used to lower/raise the blood temperature and/or maintain blood temperature, as required, through conductive heat transfer of conditioned water. The conductive heat transfer is accomplished through a blood oxygenator/heat exchanger unit, along with the use of a blanket under the patient for the re-warming phase, if desired. The complete system usually comprises the HEMOTHERM Cooler/Heater unit and reusable or disposable blanket on the O. R. Table- Adult, Pediatric, or Infant size. Available blankets are: the reusable PLASTIPAD® or GELLI-ROLL® blankets (polyurethane) and the disposable MAXI-THERM®, and MAXI-THERM® LITE blankets.

There is also an optional Remote Control, Model 414CE available that will allow the unit to be controlled from 25 or 50 feet away.

1.5 COOLING SYSTEM

The HEMOTHERM 400CE cooling system consists of:

1. Mechanical refrigeration system
2. Cool water reservoir
3. Water re-circulation pump
4. Power & control system
5. Low temperature safeties
6. Low water level cut off safety
7. Non-conductive electrical isolation refrigerant hoses

With a capacity to lower the water temperature, a reduction of blood temperature is produced. It is important to remember that there is no direct relationship between this and the rate of change in the blood temperature. The re-circulation pump and water flow circuitry have been designed for high flow rate to maximize the blood-to-water heat transfer efficiency.

The cooling system's temperature controller allows the equipment operator to set the temperature range from +3°C to +32°C. Independent Low Limit Equipment Safeties on the control board provides low limit equipment protection and is factory preset at 2°C.

This is a redundant safety system in that there are two independent Low Limit Equipment Safeties preset at 2°C.

⚠WARNING ⚠

The HEMOTHERM unit has **UL/IEC 60601-1 Class I, type BF applied parts** internal and external electrically isolated components must remain isolated before, during and after any maintenance or repair. **Improper maintenance or repair can result in patient injury or damage to the HEMOTHERM unit.**

1.6 HEATING SYSTEM

The CSZ HEMOTHERM heating system consists of:

1. Dual element Heater
2. Heat water reservoir
3. Water recirculation pump
4. Power & control system
5. High temperature safeties
6. Low water level cut off safety

The 115V / 1500 watt dual element heater has 1250 high and 250 low watt elements.
The 230V / 1750 watt dual element heater has 1500 high and 250 low watt elements.

When in cool mode, the low wattage heater will pre-warm the water to the desired temperature set point for that reservoir. While in the heat mode, the water is heated with both high and low wattage elements. It is important to remember that there is no direct relationship between the temperature in the reservoirs and the rate of change in the blood temperature.

An over temperature limit (OTL) alarm automatically monitors the actual heat side reservoir temperature and compares it to the heat side set point. If the actual display temperature increases above the set point by 1°C or more for longer than two (2) minutes the high temperature limit LED on the front panel will flash and the alarm will sound a short beep. Once the temperatures are within 1°C the alarm will clear.

If the controller should happen to fail at the 42°C set point, the HIGH TEMP. LIMIT light on the key pad will illuminate and the alarm will sound at 44°C. The primary high temperature safety is designed to automatically shut off the heaters at 44°C. The heating system will come back on after approximately a 1°C temperature drop below the heat set point.

This is a redundant system in that there is a secondary high temperature safety preset at 46°C. If the primary high temperature safety should happen to fail at 44°C, the HIGH TEMP. LIMIT light on the key pad will illuminate and alarm will sound at 46°C and the heaters will turn off automatically. If this should occur, the system should be inspected by the hospital's maintenance or engineering department. This is a Remove from Service (RFS) alarm.

1.7 WATER CIRCULATION SYSTEM

The HEMOTHERM 400CE circulation system consists of:

1. Two water reservoirs
   - Cool Reservoir - (8 qts. - 7.6 liters)
   - Heat Reservoir - (6 qts. - 5.7 liters)
2. One recirculation pump
3. Four water flow control solenoid valves
4. One water filter
5. Six quick-connect fittings
6. Interconnecting water piping

Selection of the heat or cool mode determines which water flow circuit is used.

HEAT MODE: Pump draws water from the heat reservoir and circulates it through the water filter to the quick-connect fittings connected to the device in use (blood oxygenator/heat exchanger and/or blanket). Returning water flows back into the same heat reservoir.

COOL MODE: Pump draws water from the cool reservoir and circulates it through the water filter to the quick-connect fittings connected to the external device(s). Returning water flows back into the same cool reservoir.

⚠ CAUTION ⚠
Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. Do not use deionized water. Do not use alcohol. Alcohol may cause heat exchanger, blanket, and/or unit deterioration. Do not use tap water to rinse, fill, refill or top-off water tanks.

Flow rate capacity is as follows:

For 115VAC units through 1/2" quick-connect fittings: approximately 3.4 GPM with a short hose loop and flow meter attached to the fittings.
(13 liters/minute).*

For 230VAC units through 1/2" quick-connect fittings: approximately 3.0 GPM with a short hose loop and flow meter attached to the fittings.
(11 liters/minute).*

* Actual flow rate will vary depending upon brand and model number of heat exchanger used and also upon length and type of tubing leading to and from heat exchanger.

1.8 GENERAL OPERATION

1. Collect all Supplies and Equipment:

   A. HEMOTHERM Cooler/Heater unit: Include connecting hoses to the extracorporeal circuit heat exchanger making sure that all connections are tight and secure.

   B. Extracorporeal circuit heat exchanger: Make sure that there are no leaks.

   C. Hyper-Hypothermia blanket: Make sure that there are no leaks.

⚠ WARNING ⚠
Upon receipt of the HEMOTHERM, the unit should be disinfected per the WATER SYSTEM DISINFECTION PROCEDURE. Additionally, any unit removed from storage should be disinfected. **Failure to do so could result in patient and/or caregiver infection.**
Contaminated blankets or hoses could contaminate the unit. Reusable accessories should be disinfected on a quarterly basis. **Failure to do so could result in patient and/or caregiver infection.**

2. Place HEMOTHERM unit in O.R. suite as close to the heat exchanger as possible and verify tight and secure connections to both the HEMOTHERM and extracorporeal circuit heat exchanger.

3. Read the operating instructions on the keypad and in this manual. Familiarize yourself with the name and location of all features and controls shown in this manual.

4. Check the level of the water in both fluid reservoirs to make certain they are filled to where water can be seen in bottom of the strainer. (Heat reservoir holds 6 qts. (5.7 liters) and the Cool reservoir holds 8 qts. (7.6 liters). It is necessary to add water after each use to replace water left in disposable heat exchanger and Hyper-Hypothermia blanket. Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns.

5. Make sure the power switch is in the "OFF" position.

6. Inspect the power cord plug for bent or missing prongs. Insert the plug into a properly grounded, securely mounted receptacle. Grounding reliability can only be achieved when connected to an equivalent hospital grade receptacle. Do not bypass the third or grounding prong. An electrical hazard may result if it is bypassed, removed, or otherwise rendered useless.

7. Lay the Hyper-Hypothermia blanket flat on the O.R. table with hose attachment coming off the table as close as possible to where the HEMOTHERM unit will be placed.

8. Test-Indicators: Energize and De-energize all display segments and all LED's. Press the power switch to the "ON" position.

NOTE: The HEMOTHERM unit will go through a short self-calibration procedure with both displays blank and then through a fill mode for approximately forty-five seconds. The displays will show FI on the Heat side and LL on the Cool side spelling out FILL. This allows the unit to calibrate and prime the pump automatically.

A. Press "HEAT" or "COOL" for desired mode of operation. (Flashing Temperature is set point; Non-Flashing is actual reservoir temperature). Preset temperatures are 3°C -cooling; 42°C -heating.

B. Select Cool - cool display will flash when below 10°C until pump switch is activated. Then it will display actual water temperature and the compressor will start up.

C. If you wish to change the setting, press the "Temp Set" switch. The display will flash the previous set point temperature or 3°C if the unit has just been turned on.

NOTE: You have five seconds to press one of the arrows or the temperature readout will return to the actual reservoir temperature. Press either the "up" or "down" arrow to raise or lower the set point temperature to the desired setting.

D. Press the "Cool" switch. When ready to circulate the water, press the pump switch.

⚠NOTE ⚠
The temperature cannot be set below 10°C without activating the “Pump” switch. If the operator attempts to do so, the set point temperature will flash until the “Pump” switch is activated. Then it will display the actual temperature and the compressor will activate.

E. The HEMOTHERM will automatically pre-warm the heat reservoir while cooling to the desired water temperature. To adjust the pre-warm set point, press the "Temp Set" switch. The display will flash the previous set point temperature or 42°C if the unit has just been turned on.

NOTE: You have five seconds to press one of the arrows or the temperature readout will return to the actual reservoir temperature. Press either the "up" or "down" arrow to raise or lower the set point temperature to the desired setting.

NOTE: When the compressor cycles off, full heat comes on until the temperature of the heat reservoir is within 1°C of the set point. If the compressor cycles back on, only the low wattage heater element remains on.

F. The unit will not cool below 10°C unless the pump is activated.

G. Select the "HEAT" switch. Press the "Temp Set" switch. The display will flash the previous set point temperature or 42°C if the unit has just been turned on.

NOTE: You have five seconds to press one of the arrows or the temperature readout will return to the actual reservoir temperature. Press either the "up" or "down" arrow to raise or lower the desired setting. Press the heat switch.

H. When ready to circulate the water, press the "Pump" switch.

9. After the cool water is preconditioned, proceed to connect your heat exchanger to the 1/2" quick-connect fittings.

NOTE: You may want to turn off the pump or the flow indicator shut-off valve first if you choose not to circulate cool water through the heat exchanger at this time.

10. Check physician's instructions to determine the desired cool and/or heat set point temperatures.

11. At this point, you may choose to maintain normal body temperature or you may choose to cool the blood.

12. Maintain normothermia by setting the desired temperature, pressing the heat mode switch, and making sure the pump is on. The "HEAT" temperature displayed is the water temperature circulating through the heat exchanger and the Hyper-Hypothermia blanket (if you choose to use a blanket).

    NOTE: The precision dual microprocessor controller will supply the appropriate amount of wattage to the heater in order to maintain temperature.

13. Cool the blood by setting the desired fluid temperature. Using the cool mode "temp set", you may choose 3°C for better efficiency. The "COOL" temperature displayed is the fluid temperature circulating through the heat exchanger.

    NOTE: The compressor will cycle on and off to maintain the set point temperature.

14. Maintain final hypothermia temperature by resetting the Cool set point temperature to 10°C and turning off the pump when you reach the hypothermia temperature desired. If the temperature should tend to rise, reactivate the pump allowing the cool water to circulate through the heat exchanger and as a result bring the blood temperature down again.

15. Preset your hot water temperature to the desired initial re-warming temperature.

16. The units will re-warm by activating the "HEAT" switch. The Hemotherm will receive the maximum wattage of heat to raise the hot water fluid temperature to the set point temperature. At this point, if desired, connect your Hyper-Hypothermia blanket to the 1/8" quick-connect fittings of the HEMOTHERM unit to maximize re-warming efficiency.

⚠**NOTE** ⚠
If you happen to overshoot your desired "HEAT" water temperature, you may push the "COOL" switch for five to ten seconds allowing the water in the water lines and heat exchanger to empty into the "COOL" water reservoir. Switching back to the "HEAT" mode will allow cool water in the water lines and heat exchanger to be mixed into the "HEAT" water, in turn cooling the temperature of that water a few degrees (1°- 4°C) depending on the difference in temperature between the two reservoirs. The same can be done if you overshoot your desired cool water temperature.

- To discontinue operation, simply turn off the power switch and disconnect all lines leading to the heat exchanger and/or blanket from the HEMOTHERM unit.

1.9 REMOTE CONTROL OPTION

⚠NOTE ⚠
The Model 400CE will only work with the Model 414CE Remote control and cables and is not compatible with the HEMOTHERM Model 400M or Model 400MR units.

All HEMOTHERM units are equipped with a remote control port. The remote control port connection is located on the right side of the unit, near the power switch/circuit breaker. If the remote control option is purchased, the “assembly" will include a mating 25 foot cable, the remote control unit, and a mounting clamp.

To install the remote control option, first turn the HEMOTHERM unit power switch off. Mount the remote control in a convenient place utilizing the universal mounting clamp provided. Connect the cable between the two devices and secure in place by tightening the screws attached to the cable housing. The remote control will operate the same as the key pad located on the HEMOTHERM main unit.

1.10 HEMOTHERM SYSTEM EQUIPMENT & ACCESSORIES

Cat. No.	HEMOTHERM Equipment
400CE	HEMOTHERM Dual Reservoir Cooler/Heater
414CE	Remote Control (includes UMC-1 and 25 ft cable)
420	Flow Indicator with Shutoff Valve Assembly
UMC-1	Universal Mounting Clamp

MAXI-THERM® Single-Patient Use Blankets (Vinyl)

276	Adult/O. R. Table Size (24" x 60")
274	Pediatric Size (22" x 30")
273	Infant Size (12" x 18")
286	9' Connecting Hose (Extra Length Hoses Available Upon Request)

MAXI-THERM® LITE Single Patient Use Blankets

876	Adult/O.R. Table Size (25” x 64”)
874	Pediatric Size (25” x 33”)
873	Infant Size (13” x 18”)
286	9' Connecting Hose (Extra Length Hoses Available Upon Request)

PLASTIPAD® Reusable Blankets (Polyurethane)

196CPC	PlastiPad Adult, CPC
194CPC	PlastiPad Pediatric, CPC
193CPC	PlastiPad, Infant CPC
195N	PlastiPad Narrow Adult
196	Adult/O. R. Table Size (24" x 60")
194	Pediatric Size (22" x 30")

193	Infant Size (12" x 18")
186	9' Blanket Extension Hose With Couplings (Extra Length Hoses Available Upon Request)

GELLI-ROLL® – Reusable Hypo-Hyperthermia Blanket

195P	73 x 21 x .625 inch thick
194P	31 x 24 x .625 inch thick
193P	20 x 13 x .625 inch thick
286	9' Connecting Hose (Extra Length Hoses Available Upon Request)
52103	Gelli-Roll Repair Kit

1.11 HEMOTHERM SYSTEM EQUIPMENT SPECIFICATIONS

PHYSICAL

- Dimensions:
  22” W x 22" D x 32" H
  (56cm W x 56cm D x 81cm H)
- Floor space consumed:
  484 in^2. (3,123 cm^2.)
- Weight: 200 lbs. (90.7kg.)
- Cabinet construction: 16 gauge steel
- Warm air flow: bottom (downward)

CIRCULATING SYSTEM

Reservoir Capacity:
Cool - 8 qts. (7.6 liters)
Heat - 6 qts. (5.7 liters)

Reservoir Fluid: Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns.
Reservoir Opening: Fill-able from the top
Reservoir Construction: Plastic

Flow Rate:
- 11 Liters/Minute (3.0 GPM) at 230VAC for 1/2" quick connect fittings
- 13 Liters/Minute (3.4 GPM) at 115VAC for 1/2" quick connect fittings

Maximum Pressure:
12.5 PSI - Heat Exchanger and Blanket

Connections:
- 1 Set 1/2" quick connect fittings for Heat Exchanger
- 1 Set 1/8" quick connect fittings for Blanket
- 1 Set 1/4" quick connect fittings for draining (on unit)
- 1 Additional set 1/2" quick connect fittings included for tubing

ELECTRICAL

Electrical Characteristics:
- 115VAC, 50/60HZ, 16 Amps
- 230VAC, 50/60HZ, 9 Amps

Outlets Required:
- 115VAC - 20 Amps, AC grounded hospital grade plug
- 230VAC - 15 Amps, AC grounded with European plug

Circuit Breaker Rating:
In power switch
- 115VAC, 20 Amps
- 230VAC, 15 Amps

Mains Supply Isolation:
- Two-Pole Mains Power Switch

SAFETY

Second Hi Limit Safety:
46°C ± 0.5°C

Primary Hi Limit Safety:
44°C ± 0.5°C

Low Limit Safety:
2°C ± 0.5°C

ENVIROMENTAL CONDITIONS

Temperature Range
(transportation and storage):
-40°C – 50°C (-40°F – 122°F)

Humidity (transportation and storage):
20% – 95%

COOLING SYSTEM	**CONTROL SYSTEM**
Compressor: ½ HP oversize Fluid Cooling Range: 32°C to 3°C	Fluid Temp Control Range: 3°C to 42°C Fluid Temp Control Accuracy: • Set-points 3°C-5°C and 40°C-42°C: ±0.5°C • Set-points 5°C-40°C: ± 1.0°C Fluid Temp Setting: 1°C Resolution
HEATING SYSTEM	**SERVICEABILITY**
Power Rating: 115 VAC: 1500 Watts of Heat 230 VAC: 1750 Watts of Heat Fluid Heating Range: 25°C to 42°C Time to Heat: 25°C to 42°C in 15 minutes or less	Special Tools Required - No **WARRANTY PERIOD** 1 year parts if not returned to CSZ. 1 year parts and labor if returned to CSZ

SERVICE LIFE

The expected service life / lifetime of the Hemotherm Model 400CE is **twelve (12) years** from the date of manufacture provided the product is not subject to misuse, negligence, accident or abuse and under the conditions that the device is properly used as intended, and serviced and maintained according to the Operation / Technical Manual provided with the device.

1.12 ESSENTIAL PERFORMANCE TABLE

Patient Protection ▪ Water Temperature Control ▪ Water Temperature Setpoint Limits ▪ Water High Temperature Limit ▪ Water Low Temperature Limit ▪ Low Water Level in the Reservoir ▪ Temperature Sensor Malfunction ▪ Water Flow Rate
System Pressure

1.13 HEMOTHERM CLASSIFICATION AND CERTIFICATIONS

This unit is a Class II medical device according to the US FDA CDRH.

This unit has been certified to IEC 60601-1 Class I, Type BF Applied Part.

CLASSIFIED C UL US
16HV

MODEL 400CE MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, ASTM F2196-02, CAN/CSA-C22.2 No. 601.1 AND IEC60601-1-2

This unit is Class IIb according to the Medical Device Directive MDD 93/42/EEC required by
The Council of the European Communities

CE 0344

Manufactured under the quality system requirements of ISO 13485.
Degree of protection against harmful ingress of water is IPX0.

EMC COMPATIBILITY TABLES ACCORDING TO IEC 60601-1-2

Guidance and manufacturer's declaration – electromagnetic emissions		
The Hemotherm, Model 400CE is intended for use in the electromagnetic environment specified below. The customer or the user of this unit should assure that it is used in such an environment.		
Emissions tests	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Hemotherm, Model 400CE uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Hemotherm, Model 400CE is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Hemotherm, Model 400CE is intended for use in the electromagnetic environment specified below. The customer or the user of the Hemotherm, Model 400CE should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Hemotherm, Model 400CE requires continued operation during power mains interruptions, it is recommended that the Hemotherm, Model 400CE be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The Hemotherm, Model 400CE is intended for use in the electromagnetic environment specified below. The customer or the user of the Hemotherm, Model 400CE should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Hemotherm Model 400CE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measure field strength in the location in which the Hemotherm, Model 400CE is used exceeds the applicable RF compliance level above, the Hemotherm, Model 400CE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Hemotherm, Model 400CE.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Hemotherm, Model 400CE

The Hemotherm, Model 400CE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Hemotherm, Model 400CE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Hemotherm, Model 400CE as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Supplemental certification information available on request.

SECTION 2. OPERATING INSTRUCTIONS

2.1 INITIAL SET-UP

Steps 1-10 should be followed the first time the HEMOTHERM unit is set-up. For subsequent operation, refer to General Operation Instructions.

⚠ WARNING ⚠

Upon receipt of the HEMOTHERM, the unit should be disinfected per the WATER SYSTEM DISINFECTION PROCEDURE. Additionally, any unit removed from storage should be disinfected. **Failure to do so could result in patient and/or caregiver infection.**

1. Collect proper equipment and supplies.

   A. HEMOTHERM unit.
   B. Extracorporeal circuit with blood heat exchanger.
   C. Hyper-Hypothermia blanket (optional).
   D. 17 qts. (16 liters) of sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. [The cool reservoir holds 8 qts. (7.6 liters), the heat reservoir holds 6 qts. (5.7 liters), the blanket (adult) holds 2 qts. (1.9 liters) and approximately 1.5 qts. (1.4 liters) will be required to fill the connecting lines and the heat exchanger]. No alcohol should be used.

2. Make sure power switch is in the OFF/"O" position.

3. Lift the reservoir lid and remove individual reservoir covers. Fill the cool reservoir with 8 qts. (7.6 liters) of sterile water or water that has been passed through a filter of less than or equal to 0.22 microns and the heat reservoir with 6 qts. (5.7 liters) of sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. **The level should be approximately 1" from the top of each reservoir or just covering the bottom of the strainer.**

4. Insert plug into properly grounded, securely mounted receptacle. Grounding reliability can only be achieved when connected to an equivalent hospital grade receptacle. Do not bypass the third or grounding leg. An electrical hazard may result if it is bypassed, removed or otherwise rendered useless.

5. Place HEMOTHERM unit next to or near heat exchanger, or another convenient location.

6. Lay the Hyper-Hypothermia blanket on the O. R. table with hose attachments close to where the HEMOTHERM unit will be placed during operation. Cover the blanket with a sheet or water blanket.

7. Attach the heat exchanger and the blanket connecting lines (if desired) to the HEMOTHERM unit.

8. Read operating instructions on the key pad before starting the unit. Familiarize yourself with the name and location of all features and controls shown.

9. Fill the heat exchanger and blanket by pressing the power switch to the ON/"I" position. The HEMOTHERM will go through a self-calibration procedure with both displays blank and then through a fill mode. The displays will show FI on the Heat side and LL on the Cool side spelling out FILL. Then activate the heat/cool mode switch and then the pump switch. Add more sterile water or water that has been passed through a filter of less than or equal to 0.22 microns to the reservoir of the mode selected when filling.

10. Reference Section 1.8 GENERAL OPERATION for instructions on heating or cooling.

2.2 CONNECTION PROCEDURE

1. Take the set of 1/2" quick-connect fittings and attach two, 1/2" I.D. plastic tubes long enough to reach from the HEMOTHERM unit to the blood heat exchanger. The shorter the length of tubing will usually result in a better flow rate. **The female fitting should be attached to the tube leading to the blood heat exchanger water inlet and the male fitting should be attached to the blood heat exchanger water outlet.**

2. After attaching the tubes to the heat exchanger, attach the 1/2" quick-connect fittings to the matched fittings on the lower right side of the HEMOTHERM unit (see Figure 1.1).

3. Attach the 1/8" quick-connect fittings leading from the Hyper-Hypothermia blanket to the matching set of 1/8" quick-connect fittings on the lower right hand side of the HEMOTHERM unit.

4. The air in the lines will be bled out after the pump switch is activated. Check the water level of the reservoirs after filling connecting water lines.

2.3 DISPOSAL OF WASTE PRODUCTS

⚠CAUTION ⚠
Always drain the HEMOTHERM to a sanitary drain because **bio-contaminants** may be present in the unit's water supply.

Dispose of pads in a means consistent with hospital policy protocol for patient contact items.

The unit refrigerant must be handled and disposed of according to the requirements and laws of the local authority having jurisdiction.

2.4 SAFETY CONTROLS

1. Low Limit Equipment Safety will automatically shut off the compressor if the cold water reservoir temperature is 2°C ±0.5°C. The low temperature limit LED will come on and the alarm will sound. This will also shut off the pump which will stop the circulation of water. The cooling system will come back on after approximately a 1°C temperature rise above the set point and the alarm will clear.

   Note: This is a redundant system in that there are two independent Low Limit Equipment Safeties preset at 2°C.

2. Overtemperature Limit Alarm will automatically monitor the actual heat side reservoir temperature and compare it to the heat side set point. If the actual display temperature increases above the set point by 1°C for longer than two (2) minutes the high temperature limit LED on the front panel will flash and the alarm will sound a short beep. Once the temperatures are within 1°C the alarm will clear.

3. Primary High Limit Equipment Safety will automatically shut off the heaters should the warm water reservoir temperature exceed the maximum 42°C and reach 44°C±0.5°C. The circulating pump will no longer operate. If this happens, a high temperature limit LED on the front panel will illuminate and the alarm will sound. The heating system will come back on after approximately a 1°C drop below the set point and the alarm will clear.

4. Secondary High Limit Equipment Safety is a redundant system that is safety preset at 46°C. If the device exceeds the maximum set-point of 42°C and the primary high temperature safety should happen to fail at 44°C, a high temp light on the key pad will illuminate and alarm at 46°C±0.5°C and the heaters will turn off automatically. The circulating pump will no longer operate. If this happens, a high temperature limit LED on the front panel will illuminate and the alarm will sound. **The system should be inspected by the hospital's maintenance or engineering department. This is a Remove from Service (RFS) alarm.**

5. Circuit Breaker - The HEMOTHERM unit (right side) is equipped with an over-current protection circuit breaker built into the power switch to protect the unit wiring system against possible overload.

SECTION 3. MAINTENANCE AND REPAIR

3.1 GENERAL

The HEMOTHERM Cooler/Heater unit is designed and built to be field serviceable. The repair, calibration and servicing of this unit requires no special tools, except for refrigeration repairs. However, no attempt should be made to perform any of these procedures unless the proper skills and knowledge are possessed. Repair or service of the HEMOTHERM by qualified medical personnel will not void the warranty of the unit.

⚠WARNING ⚠
Before performing any disassembly procedure, be sure the power switch is in the OFF/"O" position and the power cord is unplugged from the receptacle. **Electrical Hazards may result.**

All internal operating components are readily exposed by removing the rear panel. This is accomplished by removing the five retaining screws around the perimeter of the panel. Pull rear panel away from the unit.

Access to the condenser grille is attained by removing the air intake vent at the front of the HEMOTHERM unit. To do this, remove the four screws securing the vent to the unit.

3.2 EXTERNAL CLEANING INSTRUCTIONS

The HEMOTHERM unit and Remote Control are constructed of powder coated steel with a plastic membrane keypad. For cleaning and disinfecting, use tuberculocidal wipes. Avoid 100% alcohol and other strong, undiluted disinfectants. These may cause staining of the device's outer skin. **Wipe down the entire exterior of the device paying extra attention to crevices on the device.**

NOTE: Surfaces are to remain wet for the duration specified by the wipe's instructions. Use wipes that have bleach (sodium hypochlorite) as an active ingredient to avoid discoloration of the unit.

3.3 TEMPERATURE ACCURACY CHECK

For temperature accuracy and verification it is recommended to use a calibrated thermometer (with ±0.1°C accuracy or better) located as close as possible to the reservoir water temperature sensor. For best accuracy be certain that the thermometer is not near the heater or evaporator coil when you are taking measurements.

3.4 MAINTENANCE OF THE WATER RESERVOIRS

Monthly, at a minimum, the reservoirs should be drained, wiped down with tuberculocidal wipes and refilled with sterile water or water that has been passed through a filter of less than or equal to 0.22 microns.

CAUTION
For safe handling and use of chemicals follow manufacturer guidelines.

The reservoirs should be maintained at least once a month, more often if possible.

To empty the reservoirs, first make sure the power switch is in the OFF/"O" position. Then, attach the 1/4" female coupling of the drain tube over either of the 1/4" male fittings marked "DRAIN" on the side of the unit. Allow gravity to drain the water from the one reservoir and then repeat for the other one. If draining unit into a container, be sure that the container has a capacity of at least five gallons (13.3 liters).

Remove the reservoir covers by lifting the cover at the strainer handle. Prior to refilling, clean the underside of both reservoir lids using a tuberculocidal wipe. Clean any residue from the bottom and sides of the empty reservoir and wipe down with tuberculocidal wipes. Pay extra attention to the areas not in the water pathways, such as the lid of each reservoir, and the top section of the water reservoir.

NOTE: Surfaces are to remain wet for the duration specified by the wipe's instructions. Use wipes that have bleach (sodium hypochlorite) as an active ingredient to avoid discoloration of the unit.

Place the reservoir covers back on the proper reservoir. Refill the reservoir with sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. The capacity of the reservoirs is - 6 qts (5.7 liters) for the heat reservoir and 8 qts. (7.6 liters) for the cool reservoir. Under all circumstances, the reservoirs should be filled before starting the HEMOTHERM unit. It is not necessary to drain the reservoirs after each use.

3.5 WATER SYSTEM CLEANING & DISINFECTION PROCEDURE

Quarterly, at a minimum, the FLUID CIRCUIT CLEANING & DISINFECTION/DRY STORAGE PROCEDURE, listed below, should be conducted.

CAUTION
For safe handling and use of chemicals follow manufacturer guidelines.
Always drain the HEMOTHERM to a sanitary drain because **bio-contaminants** may be present in the unit's water supply.
Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. Do not use deionized water. Do not use alcohol. Alcohol may cause blanket and/or unit deterioration. Do not use tap water to rinse, fill, refill or top-off water tanks.

FLUID CIRCUIT CLEANING & DISINFECTION/DRY STORAGE PROCEDURE For Circulating Water Units Utilizing Household Bleach

The following procedure disinfects the fluid circuit in these products. The required tools/supplies are:

- Drain hose (P/N 93807) and Bypass hose, if applicable, (P/N 93817)
- Agency registered tuberculocidal wipes[1]
- Cleaning Agent[2]: Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner
- Disinfectant[3]: 6% bleach or 8.25% bleach
- Sterile water or water that has been passed through a filter of less than or equal to 0.22 microns
- pH strips
- Appropriate AC electrical power.

Procedure:

1. Turn unit off ("O" position).
2. Remove any blood heat exchangers, Hyper-Hypothermia blankets, and hoses that are connected to the unit.
3. Drain the water from each reservoir as described in MAINTENANCE OF THE WATER RESERVOIRS.
4. Using a tuberculocidal wipe, wipe down the reservoirs and the underside of both reservoir lids. Pay extra attention to the areas not in the water pathways, such as the lid of each reservoir, and the top section of the water reservoir.

NOTE: Surfaces are to remain wet for the duration specified by the wipe's instructions. Use wipes that have bleach (sodium hypochlorite) as an active ingredient to avoid discoloration of the unit.

[1] ARTG registered, EPA Registered, Health Canada licensed
[2] Australian Register of Therapeutic Goods (ARTG) #151419
[3] Health Canada Drug Identification Number (DIN) 6% bleach (DIN 02459116) or 8.25% bleach (DINs 02459108 or 02438100)

5. If necessary, determine the desired reusable blanket and/or hoses to be disinfected and connect them to the unit.
   5a. Only ONE (1) blanket can be attached to the Hemotherm unit for disinfection at a time.
   5b. For disinfecting hoses without a blanket, the bypass hose (P/N 93817) must be used to connect the hose's two CPC fittings.

6. Add to each reservoir the appropriate amount of Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner and sterile water or water that has been passed through a filter of less than or equal to 0.22 microns per the chart below:

RESERVOIR	Prolystica 2X Concentrate	STERILE/FILTERED WATER	TEMPERATURE
COOL HEAT	30.4 Milliliters 22.8 Milliliters	7.6 Liters 5.7 Liters	20°C 42°C

7. Turn the unit on ("I" position). Confirm that the Heat Side is set to 42°C. Set the Cool Side to 20°C. Allow both sides to reach temperature before continuing.

8. Press PUMP and circulate for the time specified in the chart below for both Cool and Heat modes. The unit utilizes an internal shunt to complete the circulation path if no accessories are attached.

	Blanket Connection/Return	Disinfecting Cycle Time per Mode
Combination 1	N/A – Hemotherm Only	5 min
Combination 2	Hemotherm, Cat #286 hose and blanket	10 min
Combination 3	Hemotherm, Cat #286 hose and Bypass hose	10 min

9. Press PUMP to stop the unit's circulation.

10. Per the below table, add the appropriate amount of bleach to the water & Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner in each reservoir.

NOTE: The type of bleach is based on the sodium hypochlorite content. This can be found on the bottle where the active ingredients are listed.

RESERVOIR	TEMPERATURE	BLEACH	
		6% Sodium Hypochlorite	8.25% Sodium Hypochlorite
COOL HEAT	20°C 42°C	320 Milliliters 235 Milliliters	230 Milliliters 170 Milliliters

11. Press PUMP and circulate for the time specified in the chart below each in both cool and heat modes. The unit utilizes an internal shunt to complete the circulation path if no accessories are attached.

	Blanket Connection/Return	Disinfecting Cycle Time per Mode
Combination 1	N/A – Hemotherm Only	5 min
Combination 2	Hemotherm, Cat #286 hose and blanket	10 min
Combination 3	Hemotherm, Cat #286 hose and Bypass hose	10 min

12. Drain each reservoir as instructed in Section 3.4.

13. Rinse the unit

13a. Refill the unit with sterile water or water that has been passed through a filter of less than or equal to 0.22 microns until the water touches the strainer for both reservoirs.

13b. Circulate the water per the chart below in both cool and heat modes.

	Blanket Connection/Return	Disinfecting Cycle Time per Mode
Combination 1	N/A – Hemotherm Only	5 min
Combination 2	Hemotherm, Cat #286 hose and blanket	10 min
Combination 3	Hemotherm, Cat #286 hose and Bypass hose	10 min

13c. Drain each reservoir as instructed in Section 3.4.

14. Repeat step 13 twice more for a total of three rinses.

15. After the third rinse, refill the unit with sterile water or water that has been passed through a filter of less than or equal to 0.22 microns until the water touches the strainer for both reservoirs. Circulate the water for 1 minute in each mode.

16. Check the water with pH strips or other appropriate test method for detecting bleach. If bleach is detected, repeat Steps 13-15.

NOTE: To avoid damage to the unit, the pH should be approximately 7. Use the guide provided with the pH strips or other appropriate test method to interpret the reading. Different strips should be used to test each reservoir.

17. If unit is being **returned to service** proceed to Step 19.
18. If unit is being **placed in dry storage** proceed to Step 20.
19. **RETURNING TO SERVICE:** Ensure that the water reservoirs are filled with sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. Turn off the unit and proceed to Step 24.
20. **FOR DRY STORAGE:** If unit is being placed in dry storage, do the following steps.
21. Drain the water from each reservoir as described in the Section 3.4.
22. When all fluid has been removed from the unit, disconnect the drain hose(s) and wipe unit clean.
23. Unit is now ready for storage. Refer to Section 1.11 for specifications for storage conditions.
24. Remove any accessories attached to the unit. Document unit maintenance per Cincinnati Sub-Zero and hospital protocol. (Maintenance records can be found in Sections 3.10 & 3.11).

When you are ready to return unit from storage, repeat the above disinfection procedure. Perform all the checks as described in this Manual.

3.6 MAINTENANCE OF THE WATER FILTER

⚠ WARNING ⚠
Always **unplug the unit** before accessing internal components during service. Failure to unplug the unit could result in **electric shock.**

The HEMOTHERM circulating system includes a water filter designed to clear the line of particulate matter as the water is pumped through the system. The water filter assembly

is a plastic T-shaped fitting that intersects the hose from the pump to the outlet manifold. A stainless steel wire-mesh screen is located inside the clear plastic cap of the water filter assembly.

Once every three months, or more often if deemed necessary, the water filter should be disassembled and cleaned. To do so, the rear enclosure panel must be removed. The cap of the water filter assembly should then be unscrewed. The wire mesh and the plastic cap should then be disinfected. The parts are then to be reassembled.

1. Press the power switch to the OFF/"O" position.

2. Disconnect the unit from its power source.

3. Drain both of the unit's water reservoirs as described in the Section 3.4.

4. Remove the five screws holding on the rear enclosure panel. Guide the panel outward towards the floor.

5. Locate the water filter assembly (shown below).

6. Firmly grasp the notched rim of the cap of the assembly and remove. The cap and hose will contain water if the unit was used prior to cleaning. The wire mesh may be lodged in the top of the fitting or it may be resting in the plastic cap.

NOTE: Water in hose lines and cap present a slip and fall hazard

7. Remove the wire mesh.

8. Clean the wire mesh and the plastic cap with a tuberculocidal wipe. Be careful not to lose the black O-ring in the rim of the plastic cap.

NOTE: Surfaces are to remain wet for the duration specified by the wipe's instructions. Use wipes that have bleach (sodium hypochlorite) as an active ingredient to avoid discoloration of the unit.

9. Replace the wire mesh in the plastic cap and position the wire mesh, O-ring and plastic cap under the fitting.

NOTE: If the black O-ring is not present in the plastic cap when the cap is returned to the unit, water can leak from the device.

10. Screw the cap clockwise on to the fitting until it is secure.

NOTE: If the plastic cap is not screwed back on at the correct angle, or is not screwed on tightly, water can leak from the device.

11. Replace the rear enclosure. Replace the five screws.

12. Document unit maintenance. (Maintenance records can be found in Sections 3.10 & 3.11).

3.7 MAINTENANCE OF THE CONDENSER GRILLE

Cool air is taken in through the grille at the front of the HEMOTHERM unit. Warm air is expelled through the bottom of the unit. Both the air intake and outlet must be kept clear when the machine is in operation.

If the condenser grille becomes covered with dust and lint, the cooling capacity of the unit will be reduced. AT LEAST EVERY MONTH THE CONDENSER SHOULD BE CLEANED. To do this, first loosen the four screws securing the condenser grille over the condenser intake. Then, remove accumulated dust or lint with a brush or vacuum. Wipe down both sides of the condenser grille with a tuberculocidal wipe. Finally, replace condenser grille and tighten all four screws.

NOTE: Surfaces are to remain wet for the duration specified by the wipe's instructions. Use wipes that have bleach (sodium hypochlorite) as an active ingredient to avoid discoloration of the unit.

3.8 MAINTENANCE OF THE HYPER-HYPOTHERMIA BLANKETS

This section describes the general maintenance and for the reusable and disposable blankets. General maintenance tasks include cleaning, draining, and storing the blankets. For further maintenance information on Cincinnati Sub-Zero blankets refer to the blanket's corresponding Instructions for Use.

PLASTIPAD® or GELLI-ROLL® Reusable Blanket

NOTE: Reusable blankets have the potential to re-contaminate the device that is connected to them.

Cincinnati Sub-Zero reusable blankets are constructed from biocompatible polyurethane/urethane. For cleaning and disinfecting, use tuberculocidal wipes. Avoid 100% alcohol and other strong, undiluted disinfectants. These may cause staining of the device's outer skin.

NOTE: Surfaces are to remain wet for the duration specified by the wipe's instructions. Use wipes that have bleach (sodium hypochlorite) as an active ingredient to avoid discoloration of the unit.

Thoroughly rinse product with clear water to remove any residue from cleaning solutions. DO NOT use gas sterilization or autoclaving for cleaning and disinfecting the blankets. To drain the water from the reusable blankets shut off the power to the unit. The blanket will drain by gravity back into the unit. Allow it to drain as much as possible before disconnecting the blanket from the unit or removing from bed, stretcher, or table.

Refer to Section 3.8 for the internal disinfection of reusable blankets and hoses.

To store PlastiPad blankets with a permanently attached hose, loosely coil the hose lengthwise into the center of the blanket. Fold the blanket lengthwise into the center, 1/3 from the left side and 1/3 from the right side. Do not fold the blankets width-wise, as doing so will crimp the tubing.

To store PlastiPad blankets without a permanently attached hose, gently fold the corner containing the tubing towards the center of the blanket. Roll or fold blanket loosely avoiding sharp creases.

Store the Gelli-Roll Pads in a dry area, in flat or rolled position (never folded). Keep pads out of direct sunlight. Keep cabinet doors and other sharp objects from coming in contact with pad surfaces at all times.

Disposal of reusable blankets per hospital/institution policy/protocol.

Disposable, Single-Patient Use Blankets

The reusable blanket maintenance procedures do not apply to the disposable, single-patient use blankets. Dispose of single-patient use blankets per hospital/institution policy/protocol.

3.9 REMOVE FROM SERVICE ALARM (RFS)

The Remove from Service (RFS) alarms are a visual and audio indication of a possible error condition in the temperature control system. The RFS alarms will require the unit to be inspected by the hospital's biomedical or maintenance department and, if required,

repaired immediately. The following are an indication that an RFS alarm condition has occurred:

- An “EE” on the HEAT side temperature display and an error number (2, 3, 5, or 6) on the COOL side temperature display.

- Temperature in the HEAT side reservoir exceeding the secondary high limit safety is also an RFS alarm and will be indicated by the HIGH TEMP. LIMIT red LED indicator and the beeper.

- A power fail condition that lasts longer than 10 seconds is also an RFS alarm and will be indicated by the POWER FAIL LIGHTS red LED indicators and the beeper.

All RFS alarms are announced by an audible beeper that cannot be muted by pressing the SILENCE ALARM button. The state of the RFS alarm is saved in the unit’s internal memory and will not clear until the error is corrected and the RFS reset sequence is performed.

Once the error condition has been corrected, the following RFS reset sequence needs to be performed to clear the alarm from the equipment‘s internal memory:

> ***Press and hold the COOL INCREMENT BUTTON and COOL TEMP SET BUTTON and SILENCE ALARM buttons to clear the RFS alarm.***

This will reset the RFS alarm, silence the audible beeper, and turn off the LED indicator.

3.10 REQUIRED QUARTERLY PREVENTIVE MAINTENANCE CHECKLIST

HEMOTHERM Model 400CE Serial No. _____

Hospital I.D. No. _____ Check when completed

1. External cabinet and controls in good condition (i.e. no dents or missing parts). □
2. All warning labels properly affixed. □
3. Quick disconnect couplings are tight, straight, and not leaking. □
4. Power cord (i.e. no cuts or exposed wire) and plug (i.e. no bent or missing pins) are in good condition. □
5. All indicator lights are operative (i.e. heat & cool modes, heaters, pump, power). (Press TEST INDICATORS BUTTON on keypad, Section 1.3) □
6. Clean water filter (See Section 3.6). □
7. Clean & disinfect water system (See Section 3.5). □
8. Leakage current check (all readings should be less than 300 micro amps for 115V units and 500 micro amps for 230V units). (See Op Tech Manual)
   - OFF normal polarity □
   - OFF reverse polarity □
   - ON normal polarity (heat) □
   - ON reverse polarity (heat) □
   - ON normal polarity (cool) □
   - ON reverse polarity (cool) □
9. Perform low limit safeties check. (See Op Tech Manual) □
10. Perform high limit safeties check. (See Op Tech Manual) □
11. Check Condition of blankets, hoses, couplings (check for leaks). (See Section 3.8) □

_____ _____

Signature of Inspector Date of Inspection

3.11 REQUIRED MONTHLY PREVENTIVE MAINTENANCE CHECKLIST

HEMOTHERM Serial No. _____

Hospital I.D. No. _____ Check when completed

1. Drain and clean reservoirs (See Section 3.4). ☐
2. Refill reservoirs with water (See Section 3.4). ☐
3. Clean condenser and grille (See Section 3.7). ☐

_____ _____

Signature of Inspector Date of Inspection

Page Intentionally Left Blank

CLASSIFIED
C UL US
16HV

CE 0344

A GENTHERM COMPANY
Cincinnati Sub-Zero Products, LLC
12011 Mosteller Road
Cincinnati, OH 45241
www.cszmedical.com

Telephone: (513) 772-8810 ■ Fax: (513) 772-9119